510(k) Summary of Safety and Effectiveness
SuturTek FASTCLOSE Device

1. Sponsor Name

Sponsor/Manufacturer:
SuturTek Incorporated
51 Middlesex Street
North Chelmsford, Massachusetts 01863
Telephone: 978-251-8088
FAX: 978-251-8585

2. Device Name

Proprietary Name: FASTCLOSE™

Common/Usual Name: Manual Surgical Instrument for General Use
Classification Name: Needle Driver
Manual Surgical Instrument for General Use (GDF)
Class I (exempt) 878.4800

Common/Usual Name:
SUTURE, NONABSORBABLE, SYNTHETIC, POLYETHYLENE
Class II 878.5000 (GAT)

SUTURE, ABSORBABLE, SYNTHETIC, POLYGLYCOLIC ACID
Class II 878.4493 (GAM)

3. Identification of Predicate or Legally Marketed Device

US Surgical Auto Suture Laparoscopic Suturing Device (K940398) US Surgical Auto Suture Endostitch (K934738)
LSI Solutions Suture Placement Device and Accessories (K981531)
Deknatel Bondek Plus Polyglycolic Acid Synthetic Absorbable (K992088)
CP Medical Polyester Nonabsorbable Surgical Sutures (K001172)

4. Device Description

The FASTCLOSE Device has four major components: 1) a reusable instrument, 2) a single-use, disposable cartridge, 3) a single-use, disposable needle, and 4) sutures.

The cartridge containing the needle (with suture attached) is loaded onto the distal end of the device. The needle is engaged by the device's internal drive mechanism and driven through the tissue to be sutured. The suture is thus passed completely through the wound. Once the suture is in place,

the device is withdrawn from the incision leaving the suture strand looped through the tissue. The two ends of the suture are then tied together in the usual manner.

5. Intended Use

The SuturTek Incorporated FASTCLOSE Suturing Device is intended for soft tissue approximation and/or ligation in general surgical procedures.

The use of this device with absorbable sutures is not indicated for use in cardiovascular and neurological procedures.

6. Comparison of Technological Characteristics

The FASTCLOSE Device is substantially equivalent in its intended use and/or function to the following predicate devices: the US Surgical Auto Suture Laparoscopic Suturing Device (K940398), LSI Solutions Suture Placement Device (K981531), the US Surgical Auto Suture Endostitch (K934738), Deknatel Bondek Plus Polyglycolic Acid Synthetic Absorbable Suture (K992088), and CP Medical Polyester Nonabsorbable Surgical Sutures (K001172).

The FASTCLOSE Device will be supplied with previously cleared suture materials.

The intended use of each of the predicate devices is open and endoscopic soft tissue approximation and fixation. The FASTCLOSE Device is used for open procedures, the same as each of the predicate devices. The operating principle of the FASTCLOSE Device is the same as that of the predicate devices: a manual instrument is used to pass needles through tissue for suturing.

7 Performance Testing

The FASTCLOSE Device performs the same function as a standard needle driver. Device have been used to approximate tissue and close wounds by placing stitches in animals (pigs, rabbits, dogs, and mice) and human cadavers. Interrupted and continuous stitches have been placed in different types of tissues including muscle, cartilage, fascia, surface and interior tissues of the heart, ligaments, hollow organs, blood vessels, and bowel. Monofilament and braided suture materials, and taper point and cutting point needles have been utilized in the test devices. The performance of the SuturTek device was compared to that of hand suturing utilizing the same materials and same tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2001

SuturTek, Inc.
c/o Ms. Debbie Iampietro
QRC Consulting
7 Tiffany Trail
Hopkinton, Massachusetts 01748

Re: K011105
Trade/Device Name: FASTCLOSE Suturing Device
Regulation Number: 878.4830
878.4800
Regulatory Class: II
Product Code: GAL, GAB, HCF
Dated: April 10, 2001
Received: April 11, 2001

Dear Ms. Iampietro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011105

Device Name: FASTCLOSE Suturing Device

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

for Mark N Milhous
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011105